

CLAIMS

What is claimed is:

1. A system for supporting a female urethra, comprising:
an introducer needle having a first end and a second end, each said end having a flattened portion with an opening therethrough;
a handle having a latch mechanism which engages the opening in the flattened portion of the first end of the introducer needle;
an implant member having an end; and
a connector joining the end of the implant member to the flattened portion of the second end of the introducer needle.
2. A system according to claim 1, wherein the introducer needle is curved and symmetrical.
3. A system according to claim 1, wherein the flattened portion of the first end differs in at least one of size and shape from the flattened end of the second portion.
4. A system according to claim 1, wherein the introducer needle has a flared section having a cross-sectional profile that, in a given direction, is at least as large as a cross-sectional profile of the connector in the given direction.
5. A connector for attachment to an end of an implant member and an introducer needle including a flat spatulated section having an opening, comprising:
a central portion;

a first arm pivotally mounted to the central portion and having a first opening at a first end; and

a second arm pivotally mounted to the central portion and having a first projection extending therefrom, the first projection being positioned so that when the first arm and the second arm move together, the first projection is received in the first opening.

6. A connector according to claim 5, further comprising an implant attachment structure to which the implant member is connected.

7. A connector according to claim 6, wherein the implant attachment structure is connected to the implant member by at least one of a suture, an adhesive, a press-connector, and a thermal process.

8. A connector as in claim 5, further comprising:
a first tooth protruding from said first arm toward said second arm; and
a second tooth protruding from said second arm toward said first arm.

9. A connector as in claim 8, further comprising a third tooth protruding from said second arm toward said first arm, wherein the first, the second and the third teeth are arranged so that when the first and the second arms move together, the first tooth is located between the second tooth and the third tooth.

10. A connector as in claim 5, further comprising a boss protruding upward from said first arm toward said second arm.

11. A connector as in claim 10, wherein the boss is "+"-shaped.

12. A connector according to claim 6, wherein the implant attachment structure comprises:

a third arm pivotally mounted to the central portion and having a second opening at a second end; and

a fourth arm pivotally mounted to the central portion and having a second projection extending therefrom, the second projection being positioned so that when the third arm and the fourth arm move together, the second projection is received in the second opening.

13. A connector as in claim 12 wherein at least one of said first, second, third and fourth arms includes a living hinge portion.

14. A connector according to claim 5, wherein said central portion comprises a first portion and a second portion, and said first and said second portions are pivotally mounted together.

15. A connector according to claim 14, wherein said first and said second portions are connected by a living hinge.

16. A connector for attachment to at least one of an implant member and an introducer needle including a flat spatulated section having an opening, comprising:

an elongated base portion having a first engaging structure at a first end and a second engaging structure at a second end;

a first arm pivotally mounted to the elongated base portion and having a third engaging structure, the third engaging structure being positioned so that when the first arm

pivots toward the elongated base portion, the first and the second engaging structures meet and engage; and

a second arm pivotally mounted to the elongated base portion and having a fourth engaging structure, the fourth engaging structure being positioned so that when the second arm pivots toward the elongated base portion, the second and fourth engaging structures meet and engage.

17. A connector as in claim 16, wherein at least one of the first and third engaging structures has an opening, and at least one of the first and third engaging structures has a projection, and the opening and the projection are arranged so that the projection enters the hole when the first arm pivots toward the elongated base portion.

18. A connector as in claim 16, wherein at least one of the second and fourth engaging structures has an opening, and at least one of the second and fourth engaging structures has a projection, and the opening and the projection are arranged so that the projection enters the hole when the second arm pivots toward the elongated base portion.

19. A connector as in claim 16, wherein said elongated base portion and said first and said second arms are integrally formed.

20. A connector as in claim 16, further comprising a rib extending from said elongated body portion, wherein said first arm and said second arm both extend from said rib.

21. A connector as in claim 20, wherein said elongated base portion, said first and said second arms, and said rib are integrally formed.

22. A connector as in claim 16, wherein at least one of said first arm and said second arm includes a living hinge portion.

23. A connector as in claim 17, wherein said projection includes a flange dimensioned and disposed so that when said projection is received in said opening, said flange secures said projection in said opening.

24. A connector for attachment to at least one of an implant member having an arm and an introducer needle including a flat spatulated section having an opening, comprising:

an elongated base portion having a first engaging structure;

an arm pivotally mounted to the elongated base portion and having a second engaging structure, the second engaging structure being positioned so that when the arm pivots toward the elongated base portion, the first and the second engaging structures meet and engage; and

an attachment point for connection to an implant member.

25. A connector as in claim 24, wherein at least one of the first and the second engaging structures has an opening, and at least one of the first and second engaging structures has a projection, and the opening and the projection are arranged so that the projection enters the hole when the arm pivots toward the elongated base portion.

26. A connector according to claim 22, wherein the attachment point is joined to the implant member using at least one of a staple, a rivet, an adhesive and a suture.

27. An introducer needle for use in a surgical procedure, comprising:

a central portion;

a first flat spatulated section and a second flat spatulated section, said second flat spatulated section being integral with said central portion, wherein the first flat spatulated section has a tip and a constant width portion disposed between the tip and the central portion, and both said flat spatulated sections have an opening formed; and

a flared section connecting the first flat spatulated section to the central portion, the flared section having a cross-sectional profile that, in a given direction, is at least as large as a cross-sectional profile of the first flat spatulated section.

28. An introducer needle according to claim 27, wherein said first and said second flat spatulated sections have substantially the same shape.

29. An introducer needle according to claim 27, wherein said tip is rounded.

30. An introducer needle according to claim 27, wherein the introducer needle has an asymmetric shape.

31. An introducer needle according to claim 27, wherein each of said spatulated sections has a tip, and the tip of the first spatulated section has a first configuration and the tip of the second spatulated section has a second configuration that is different from the first configuration.

32. An introducer needle according to claim 27, wherein said central portion has a circular cross section.

33. An introducer needle according to claim 27, wherein said central portion has an oval cross section.

34. An introducer needle according to claim 27, wherein said introducer needle is arcuate.

35. An introducer needle for use in a surgical procedure, comprising:
a first flat spatulated section;
a straight portion connected to a distal end of said first flat spatulated section;
a curved portion connected to a distal end of said straight portion;
a second flat spatulated section; and
a flared section connected to a distal end of said curved portion and connected, at its distal end, to the first flat spatulated section, the flared section having a cross-sectional profile that covers a cross-sectional profile of the first flat spatulated section,
wherein at least one said flat spatulated section has a tip and a constant width portion disposed between the tip and the central portion, and an opening formed in that said flat spatulated section.

36. An introducer needle as in claim 35, wherein the first flat spatulated section, the flared section, the straight portion, the curved portion, and the second flat spatulated section are all integrally formed.

37. An introducer needle for use in a surgical procedure, comprising:
a body portion having a proximal straight portion integral with a distal curved portion;
a handle receiving the proximal end of the straight portion; and

a flat spatulated section having a "T"-shaped cavity located at the distal end of the curved portion into which a filament can be introduced.

38. An introducer needle according to claim 37, wherein the handle is permanently attached to the proximal end of the straight portion.

39. An introducer needle for use in a surgical procedure employing a filament, comprising:

a tubular body having a proximal end, a distal end and a lumen;

a rod movably disposed in the lumen;

a needle tip movably disposed in the lumen at the distal end of the tubular body and attached to the rod, the needle tip having a cavity therein for receiving the filament, the cavity being covered by the distal end of the tubular body when the needle tip is at a rearward position,

wherein when the rod is moved toward the distal end of the tubular body the needle tip moves forward and the cavity is exposed.

40. An introducer needle according to claim 39, further comprising:

a pushbutton connected to the rod; and

an elastic member operatively associated with the pushbutton to pull the rod toward the proximal end of the tubular body so that the opening in the needle tip is covered by the distal end of the tubular body.

41. An introducer needle according to claim 39, wherein the needle tip has at least one groove formed therein for receiving the filament.

42. An introducer needle for use in a surgical procedure, comprising:
a body portion having a curved portion;
a flared section located at the distal end of the curved portion; and
a flat spatulated section having a "T"-shaped opening located at the distal end of the flared section, a leg of the "T" extending to an edge of the flat spatulated section.

43. An introducer needle for use in a surgical procedure, comprising:
a body portion having a curved portion;
a flared section located at the distal end of the curved portion; and
a flat spatulated section having an internal opening located at the distal end of the flared section.

44. An introducer needle according to claim 43, wherein the internal opening is "H"-shaped.

45. An introducer needle according to claim 43, wherein the internal opening is substantially rectangular and a central portion of the internal opening is larger in width than another part of the internal opening.

46. A handle for an introducer needle having a flat spatulated section having an opening, comprising:
a housing having an elongated portion, the elongated portion having a distal end with an opening therethrough, the opening being dimensioned to receive the flat spatulated section and hold the flat spatulated section in a connecting position in the housing;
an elastically-biased latch portion having a projection dimensioned and disposed so that when the flat spatulated section is received by the opening and is held in the

connecting position, the projection cooperates with the opening to secure the handle to the introducer needle.

47. A handle according to claim 46, wherein the housing comprises a first shell portion and a second shell portion mated together.

48. A handle according to claim 47, further comprising an insert having a slot dimensioned to receive the flat spatulated section, the insert being disposed between the first shell portion and the second shell portion.

49. A handle according to claim 47, further comprising a spring pressing against the latch portion to elastically bias the latch portion.

50. A handle according to claim 47, wherein the latch portion comprises a latch member contained in the housing, the latch member having a central pivot, a curved section located proximally relative to the pivot to generate a biasing force when the handle is assemble, and an end catch section located distally relative to the pivot, the end catch section having a projection dimensioned and disposed so that when the flat spatulated section is received by the opening and is held in the connecting position, the projection passes through the opening to secure the handle to the needle.

51. A handle according to claim 47, wherein the latch portion is an integral part of the housing.

52. A handle according to claim 47, further comprising a weight disposed within said housing.

53. An implant member for supporting a female urethra, comprising:
a central portion having a first side and a second side;
a first arm section integral with the first side of said central portion and a
second arm section integral with the second side of said central portion,
wherein at least one of said first and said second arm sections has an irregular
border.

54. An implant member according to claim 53, wherein said central
portion has smooth edges.

55. An implant member according to claim 53, wherein said at least one of
said central portion and said first and second arms has an edge having a plurality of slits
formed therein.

56. An implant member according to claim 53, wherein the first and the
second arm sections each have a plurality of openings running therethrough.

57. An implant member according to claim 53, wherein the openings are
arranged along a lengthwise axis of the implant member.

58. An implant member according to claim 53, wherein the openings are
arranged in a two-dimensional pattern.

59. An implant member according to claim 56, wherein the openings are
arranged in regular pattern.

60. An implant member comprising an elongated body made of a flexible material having a first end, a second end and a support portion, the support portion having an axis running along a length of the implant member, the support portion having a plurality of slits arranged along at least a portion of the axis.

61. An implant member according to claim 60, wherein the slits are selected from the group consisting of V-shaped, semicircular, rectangular, oval and arrowhead-shaped.

62. An implant member according to claim 60, wherein each of the first and the second ends has an opening therein.

63. An implant member according to claim 60, wherein the support portion has a width that is constant.

64. An implant member according to claim 60, wherein a width of the central portion changes at a center of the implant member.

65. An implant member comprising an elongated body made of a flexible material having a first end, a second end and a support portion, the support portion having an axis running along a length of the implant member, the support portion having a plurality of holes therethrough.

66. An implant member according to claim 65, wherein the holes are selected from the group consisting of triangular, rectangular, round, oval and irregular.

67. An implant member comprising:

a central portion having a first end and a second end;
a first arm joined to the first end; and
a second arm joined to the second end.

68. An implant member according to claim 67, wherein the central portion is made of a first material and the first and second arms are made of a second material.

69. An implant member according to claim 68, wherein the first material is a natural material and the second material is a synthetic material.

70. An implant member according to claim 68, wherein the first material is derived from dermal tissue and the second material is a synthetic mesh.

71. An implant member according to claim 67, wherein the first and second arms are joined to the central portion by at least one of a suture, a rivet, an adhesive material and ultrasonic bonding.

72. An implant member comprising: an elongated body having a first end, a second end, and a support portion, the support portion having a plurality of slits formed therein.

73. An implant member according to claim 72, wherein the first and the second ends do not have slits therein.

74. An implant member according to claim 72, wherein at least one of the first and the second ends has an opening formed therein.

75. An implant member according to claim 72, further comprising an enlarged portion that is approximately centrally located.

76. An implant member comprising a body having a first section, a second section and a third section, the second section being located between the first and the third sections, the first and the third sections each having a plurality of slits formed therein.

77. An implant member according to claim 76, wherein at least some of the slits open when a tensile force is applied to the body

78. An implant member according to claim 76, wherein the slits in at least one of the first and the third sections are arranged in a plurality of rows.

79. An implant member according to claim 78, wherein at least some of the rows are parallel to each other.

80. An implant member according to claim 76, wherein the body has a longitudinal axis and the slits lie on lines extending perpendicular to the longitudinal axis.

81. An implant member according to claim 76, wherein the slits in at least one of the first and the third sections are arranged in a first row and a second row, and the slits in the first row are staggered in position relative to the slits in the second row.

82. An implant member according to claim 78, wherein the first row is adjacent to the second row.

83. An implant member according to claim 78, wherein the slits in a first said row are uniformly spaced and the slits in a second said row that is adjacent to and in registry with the first said row are uniformly spaced and arranged so that the slits in the second said row do not lie directly adjacent to the slits in the second said row.

84. An implant member according to claim 76, wherein the slits are formed so that the implant member has a slit ratio of approximately 1.5:1.

85. An implant member according to claim 76, wherein the body comprises natural material.

86. An implant member according to claim 76, wherein the body comprises acellular porcine dermal tissue.

87. An implant member according to claim 76, wherein the body is made from a material that has been treated to maintain its shape in the absence of an applied force so that the slits are held open as holes.

88. An implant member, comprising:
a first extension loop filament;
a second extension loop filament; and
a support section having a first end having a first hole and a second end having a second hole, the first extension loop filament passing through the first hole and the second extension loop filament passing through the second hole.

89. An implant member according to claim 88, further comprising:

a first connector joined to the first extension loop filament and having a structure for attachment to a needle tip; and

a second connector joined to the second extension loop filament and having a structure for attachment to the needle tip.

90. An implant member according to claim 89, wherein the structure for attachment to a needle tip comprises a pair of movable jaws that close around the needle tip, the jaws having a structure including a projection with an enlarged end portion and a corresponding opening which secure the jaws together once the jaws have moved to close around the needle tip.

91. An implant member according to claim 89, wherein the structure for attachment to a needle tip comprises a base attached to the extension loop, the base having a projection, the projection being dimensioned to be received in a slot in the needle tip.

92. An implant member according to claim 91, wherein the projection is cylindrical.

93. A method of manufacturing an implant member, comprising the steps of:

providing a body; and

forming a plurality of slits in the body.

94. A method according to claim 93, wherein the slits are dimensioned and disposed so that the slits open when a tensile force is applied to the body

95. A method according to claim 93, wherein the slits are arranged in a plurality of rows.

96. A method according to claim 93, wherein at least some of the rows are parallel to each other.

97. A method according to claim 93, wherein the body has a longitudinal axis and the slits are arranged perpendicular to the longitudinal axis.

98. A method according to claim 93, wherein the step of forming the slits comprises using a skin graft mesher to create the slits in the body.

99. An method according to claim 93, wherein the slits are arranged in a first region and a second region, and the first and separate regions are located on opposite sides of a central region that does not have any of the slits.

100. A method according to claim 93, wherein the slits are arranged in a plurality of rows, and the slits in each row are staggered in position relative to the slits in an adjacent said row.

101. A method according to claim 100, wherein the slits in a first said row are uniformly spaced and the slits in a second said row that is adjacent to the first said row are uniformly spaced and arranged so that the slits in the second said row do not lie directly adjacent to and in registry with the slits in the second said row.

102. A method according to claim 93, wherein the slits are formed so that the body has a slit ratio of approximately 1.5:1.

103. A method according to claim 93, wherein the body comprises natural material.

104. A method according to claim 93, wherein the body comprises acellular porcine dermal tissue.

105. A method according to claim 93, further comprising the steps of:
applying tension to the body so that body takes on an elongated shape wherein the slits open to form holes; and

subjecting the body having the slits to a treatment which fixes the body in to the elongated shape in the absence of the applying of tension.

106. A method of providing support for a female urethra, comprising the steps, not limited to the following order, of:

(a) creating at least one incision in the patient's abdominal wall at the level of the pubic symphysis;

(b) creating an incision in the anterior vaginal wall just below the urethral meatus;

(c) advancing an introducer needle into the retropubic space via the incision in the patient's abdomen and downward until the needle is exposed at the vaginal incision;

(d) connecting one end of an implant member to the end of the introducer needle protruding from the vaginal incision using a permanent connector; and

(e) withdrawing the introducer needle through the abdominal incision with the implant member attached.

107. A method according to claim 106, further comprising the step of (f) repeating steps (c)-(e) on the contralateral side using a second needle and a second connector so that the implant member forms a U-shaped loop beneath the urethra, at least one of the ends of the U being available at the abdominal incision.

108. A method according to claim 106, further comprising the step of (f) positioning the implant member loosely under the urethra by at least one of pulling on the abdominal end of the implant member and by loosening the implant member by pulling on the implant member with a clamp at the vaginal incision

109. A method according to claim 106, further comprising the steps of:

- (f) attaching a handle to the introducer needle;
- (g) detaching the handle from the introducer needle; and
- (h) attaching the handle to a second needle.

110. A method of providing support for a female urethra, not limited to the following order, comprising the steps of:

- (a) creating at least one incision in the patient's abdominal wall at the level of the pubic symphysis;
- (b) creating a second incision in the anterior vaginal wall below the urethral meatus;
- (c) advancing an introducer needle through the vaginal incision upward until the introducer needle tip is exposed through the first abdominal incision;
- (d) connecting one end of an implant member to the end of the introducer needle protruding from the vagina using a permanent connector; and

(e) drawing a portion of the implant inward through the vaginal incision and through the first abdominal incision.

111. A method according to claim 110, further comprising the step of (f) repeating steps (a) and (c)-(e) on the patient's contralateral side using a second needle and a second connector so that the implant member forms a U-shaped loop beneath the urethra, at least one of the ends of the U being available at the first incision.

112. A method according to claim 110, further comprising the step of (f) positioning the implant member loosely under the urethra by at least one of pulling on the abdominal end of the implant member and by loosening the implant member by pulling on the implant member with a clamp at the vaginal incision

113. A method according to claim 110, further comprising the steps of:

- (f) attaching a handle to the introducer needle;
- (g) detaching the handle from the introducer needle; and
- (h) attaching the handle to a second needle.

114. A method of providing support for a female urethra, comprising the steps, not limited to the following order, of:

- (a) creating an incision in the anterior vaginal wall just below the urethral meatus;
- (b) connecting one end of an implant member to the distal end of the introducer needle;
- (c) advancing an introducer needle and implant member into the endopelvic fascia;

- (d) removing the introducer needle from the incision.

115. A method according to claim 114, further comprising the step of (e) repeating steps (b)-(d) on the contralateral side so that the implant member forms a U-shaped loop beneath the urethra, at least one of the ends of the U being available at the abdominal incision.

116. A method according to claim 114, further comprising the steps of:

- (e) attaching a handle to the introducer needle;
- (f) detaching the handle from the introducer needle; and
- (g) attaching the handle to a second needle.